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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/917,274 | 07/30/2001 | Jean Francois Michelet | P66901US0 | 8035 |

7590 06/03/2005

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| EXAMINER |
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YU, GINA C

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| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/917,274

Applicant(s)

MICHELET ET AL.

Examiner

Gina C. Yu

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 4, 2004, November 9, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of supplemental amendment filed on November 9, 2004 and remarks filed on November 4, 2004. Claims 1-21 are pending. The nonstatutory double patenting rejection made over claims 17-36 of copending application no. 10/345399 is maintained for the reasons of record. Claim rejections made under 35 U.S.C. § 112 are modified to address the newly added claim and a fully English translation of previously cited abstract, Katsu et al. (CAPLUS Acc. No. 1987:55617).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-36 of copending Application No. 10/345,399.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims claim a method of using a composition comprising a prostaglandin EP-2 receptor antagonist, a prostaglandin EP-4 receptor

antagonist, or the combination thereof; and EP-3 receptor agonist in a cosmetically acceptable medium, further comprising at least one additives and/or organic solvents having overlapping limitations. See claims 1 and 5 of instant application; claims 17 and 21 of 10/345,399. Both applications require topically applying a composition having same limitation to attenuate or reduce the growth of hair on a subject.

Applicants' argue that the copending application no. 10/345,399 and the present invention do not claim the same method. Examiner respectfully disagrees, as claim 5 of the instant application and claim 21 of the '399 application both require the method of attenuating or reducing the growth of hair by topically applying a composition comprising a hair growth inhibiting prostaglandin EP-2 or EP-4 receptor antagonist, or the mixture thereof; and a prostaglandin EP-3 receptor agonist.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' specification and prior art do not enable the claimed method of attenuating or reducing the growth of hair by using the recited composition. The specification and prior art do not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim without undue experimentation.

Factors to be considered in determining whether any necessary experimentation is "undue" include, but are not limited to: the breadth of the claims; the nature of the invention; the state of the prior art, the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See In re Wands, 858 F.2d 731, 737, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988).

The enablement for "a method for attenuating or reducing the growth of hair" using "hair growth inhibiting prostaglandin EP3 receptor agonists" is entirely contrary to the knowledge known in the art. Applicants argue that "virtually no experimentation is required" if the claimed prostaglandin EP-3 receptor agonists are "hair growth inhibiting", and "to find out whether it meets that definition is merely a routine matter". Examiner respectfully reiterates that the test for enablement is whether, if any experimentation is necessary, it is undue. In response to applicants' request to supply the authority for the examiner's position, see In re Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). (The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue).

See also In re Certain Limited-Charge Cell Culture Microcarriers, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd*, sub nom. (The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation); Massachusetts Institute of Technology v. A.B. Fortia, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985); In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404.

In this case, undue experimentation is necessary to make and/or use the claimed invention because, while applicants disclose that prostaglandin PGE1 is a preferred prostaglandin EP3 receptor agonists, it is well known in the art that prostaglandin PGE1 actually promotes human hair growth. A full English translation of Katsu et al. (CAPLUS Acc. No. 1987:55617) is supplied in response to applicants' request. The translation specifically teaches that prostaglandin E1 (PGE1) has an excellent hair-growth promotion action. See Detailed Explanation of the Invention. The reference teaches that clinical experiments have confirmed that PGE1 promotes hair growth to hair-loss patients when topically applied as a drug for external use. Embodiment 2 shows a formulation comprising hydrophilic solvent (ethanol), polyfunctional alcohol (butylenes glycol), surfactants (glycerine monostearate) and lipophilic actives (stearyl acid and stearyl alcohol), which are the limitations of claims 6-11 of the instant application. The reference teaches using 0.5-10 ug/ml of PGE1 in the form of alcohol lotion, aqueous solution, emulsion cream with the pH adjusted to 5-7, which are also claimed in instant claims 13-14. The reference teaches that the patients had complete recovery of head hair loss (alopecia areata) after 3-4 months of administration of the drug. Thus, the

claimed method of attenuating or stopping hair growth by topically applying or PGE1 is clearly not enabled.

Response to Arguments

Applicant's arguments filed on November 9, 2004 have been fully considered but they are unpersuasive as discussed above.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

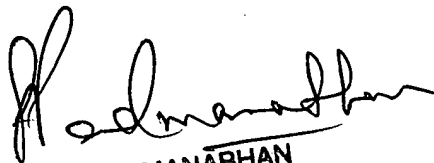
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu
Patent Examiner



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER